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## Review

# Unresolved matters related to implantable cardioverter defibrillators: How can we avoid shock therapy?

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## ABSTRACT

Implantable cardioverter defibrillators (ICDs) have become very useful for patients with a high risk of sudden cardiac death, based on the results of several clinical trials. Although ICDs can improve survival when used in patients with heart failure (HF) and reduced left ventricular (LV) function, a recent sub-analysis of major clinical trials regarding ICDs has revealed that ICD shock is associated with worsening HF or increase in mortality. ICD settings must be programmed appropriately, guided by clear evidence, to avoid unnecessary and inappropriate shocks. We discuss the benefits and pitfalls of ICD programming, such as tachycardia pacing, detection intervals, detection rates, and discriminators, to offer programming tips in this review.

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## 1. Introduction

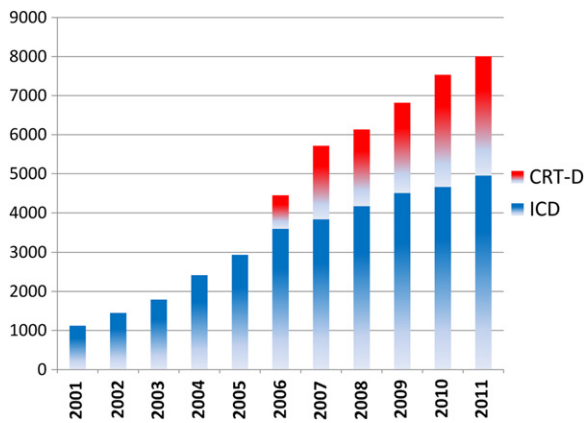
Several clinical trials [1–4] such as MADIT II [3] and SCD-HeFT [4], have shown strong evidence regarding implantable cardioverter defibrillator (ICD) use in patients with a high risk of sudden cardiac death. Based on this evidence, the American College of Cardiology/American Heart Association/Heart Rhythm Society 2008 guidelines [5] and Japanese Circulation Society 2006 Guidelines for Non-Pharmacotherapy of Cardiac Arrhythmias, which was revised in 2011 [6], recommend ICD indications for primary prevention to include patients with ischemic or non-ischemic cardiomyopathy, a left ventricular (LV) ejection fraction  $\leq 35\%$ , and New York Heart Association (NYHA) function class III or IV

Since the publication of these guidelines, more than 4000 patients have undergone implantation of ICD every year in Japan (Fig. 1). Although ICD improves survival when used in patients with heart failure (HF) and reduced LV function, a recent sub-analysis of major clinical trials of ICDs has revealed that ICD shock is associated with worsening HF or increase in mortality [7–10]. Accordingly, it is important to avoid ICD shock, particularly inappropriate shock, in patients with HF and reduced LV function.

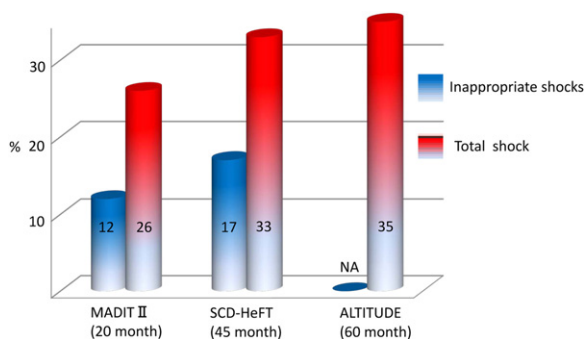
## 2. Incidence of ICD shocks and association with mortality

Current data suggest that about one third of HF patients with ICD for primary prevention receive ICD shock during their follow-up periods (Fig. 2). The MADIT II study showed that 20% of study subjects received ICD shock therapy with an annual shock rate of 5.6% and the incidence of inappropriate shock was 27%, with an

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**Fig. 1.** Annual implantation numbers for ICDs and CRT-Ds in Japan. The annual implantation numbers for ICDs and CRT-Ds have been increasing rapidly, and recently, more than 4000 patients have undergone ICD implantation every year in Japan.



**Fig. 2.** Incidence of total and inappropriate shocks in the MADIT II, SCD-HeFT, and ALTITUDE studies. Large trials such as MADIT II, SCD-HeFT, and ALTITUDE, have shown that the occurrence of both inappropriate and total ICD shocks is high.

annual shock rate of 7.5%. In the SCD-HeFT study, the incidence of appropriate shock was 21% of the ICD arm at 45 months and the incidence of inappropriate shock occurred in 17% of the ICD arm.

After an ICD shock, either appropriate or inappropriate, it was reported that hospitalization for HF events and mortality rate increased. Moss et al. reported that mortality was increased 3-fold with frequent hospitalization for HF after an appropriate ICD shock and the survival rate after the first appropriate ICD shock was 80% at 1 year, which was significantly lower compared with survival without ICD shock [7]. Moreover, the occurrence of an inappropriate ICD shock was associated with a hazard ratio for mortality of 2 [8]. Based on sub-analysis of the MADIT II study, ICD shock therapy was associated with a 39% increased risk of a first hospitalization for HF and a 58% increase in recurrent admission for HF [9]. In addition, according to the SCD-HeFT study, patients receiving an appropriate ICD shock had a 5-fold increase in risk of mortality and patients receiving an inappropriate ICD shock had a 2-fold increase in risk of mortality; these results are similar to the MADIT II sub-analysis data [10]. Based on these data, therapeutic shocks for spontaneous ventricular tachyarrhythmia are at increased risk. However, an adverse prognosis after shocked spontaneous ventricular tachyarrhythmia can only be related to underlying heart disease. As for inappropriate ICD shock, in the ALTITUDE study, which included 28,000 patients for primary prevention, inappropriate shock for sinus tachycardia or for noise oversensing was unrelated to increased mortality (HR 0.97; 95% CI 0.68–1.37 and HR 0.91; 95% CI 0.50–1.67, respectively) after adjustment for age, sex, and implantation data [11]. Underlying cardiac disease can cause ventricular arrhythmias or atrial fibrillation, in contrast to the shocks

themselves, leading to increased mortality. Although ICD shocks in normal rhythm have adverse effects in experimental conditions, such as electrical shock trauma of irreversible electroporation of the cell membrane [12–14], Bhavnani et al. reported that there was no correlation between ICD shock delivered against induced ventricular arrhythmias and increased risk of all-cause mortality and hospitalization for HF, compared with patients without induction of ventricular arrhythmia; they concluded that ICD shocks for induced ventricular arrhythmias did not increase the risk of mortality or HF hospitalization significantly [15]. There is a room to argue whether correlation between ICD shocks and subsequent mortality is due only to a patient's underlying heart disease or whether ICD shocks themselves have an independent causal role. However, we must reduce ICD shocks as much as possible because they induce adverse psychosocial consequences, such as unpleasant anxiety and anticipation of the next shock.

### 3. Benefits and tips for antitachycardia pacing

To reduce ICD shocks, antitachycardia pacing (ATP) for terminating lethal ventricular tachyarrhythmias must be programmed. There are 2 main types of ATP: burst (scan) pacing and autodecremental overdrive pacing (ramp pacing). Programming ATP is common for ventricular tachycardia (VT) but there are a few data regarding detailed settings. With regard to the different types of pacing (burst pacing or ramp pacing), there were no significant differences in terminating VT episodes with cycle length (CL) more than 320 ms between burst pacing and ramp pacing [16,17]; however, in the case of fast VT episodes with CL between 240 and 320 ms, burst pacing was more effective for terminating VT episodes compared with ramp pacing [18]. Many episodes labeled by ICD as ventricular fibrillation (VF) are sometimes rapid monomorphic VT, particularly when the CL of VT was between 240 and 320 ms. Wathen et al. reported that an ATP setting with an 8-pulse burst with pacing train at 88% of VTCL was successful in terminating rapid VT with CL less than or equal to 320 ms in 72% of study subjects [19]. Interestingly, the success rate of burst pacing against rapid VT was higher with 2 sequences compared with only one sequence [20]. The second sequence terminated 35% of rapid VT. Moreover, we cannot conclude that ATP was not effective after failing to terminate rapid VT because one failure of an ATP sequence did not predict subsequent failure; thus ATP should be set for rapid VT at all times. According to the number of stimuli and coupling intervals, Peinado et al., compared 4 settings, including burst CL at 91% or 81% of VTCL with 7 or 15 stimuli, and reported that 15 stimuli with a burst CL at 91% of VTCL was the most effective in terminating VT [21]. However, a recent report of the ADVANCED-D trial suggested no significant differences between groups with 8 stimuli and 15 stimuli, with regard to terminating VT with a CL between 240 to 320 ms by burst pacing [22]. In cardiac resynchronization therapy devices with defibrillators (CRT-Ds), we can select the pacing mode BiV (right ventricular [RV] pacing with simultaneous LV pacing) or RV only pacing, as ATP in some devices. Gasparini et al. reported that the efficacy of the first ATP in terminating any VT was similar in both groups of BiV ATP and RV only ATP [23]. However, sub-analysis revealed that BiV ATP was more effective for fast VT with CL between 240 and 320 ms in patients with ischemic heart disease compared with RV only ATP. Based on these data, we should select BiV ATP, particularly in patients with ischemic heart disease.

### 4. Detection intervals and rates

Non-sustained VTs are often detected by ICD devices, which do not require ICD therapy, particularly ICD shock. Thus, it is very

important to set a detection interval to recognize whether the arrhythmias have continued or stopped. Although there is a recent trend to use a longer detection interval, we should consider that it is somewhat arbitrary, depending on the patient's situation and clinical background, such as ICD indication, baseline LV function, drug use, etc., because longer detection intervals may cause arrhythmic syncope or delay therapy. In the PainFree II study, the detection intervals were set to 18/24 intervals and 34% of fast VTs were self-terminating in the fast VT zone between 240 ms and 320 ms [19]. Whereas only 1% of ventricular arrhythmias in the VF zone spontaneously terminated using detection criteria of 12/16 intervals in PainFree I [24]. The PainFree II study suggests that a longer delay will reduce unnecessary device detection and therapy. It is, however, likely that a longer duration of tachycardia detection might increase cases of syncope, resulting from delays in therapy. However, longer detection intervals in the PainFree II study (18/24 intervals) proved safe because arrhythmic syncope did not increase compared with PainFREE I. Taking into account recent evidence from the PREPARE [25] and RELEVANT studies [26], we should adopt a longer duration to avoid ICD shocks in primary prevention patients with ICD or CRT-D. The PREPARE study patients were less likely to receive a shock in the first year compared with control patients (9% vs. 17%,  $P=0.01$ ). The incidence of untreated VT and arrhythmic syncope was similar between the PREPARE study patients and the control cohort. Likewise, in the RELEVANT study of CRT-D patients with non-ischemic heart disease and primary prevention, whose detection interval was much longer in the protect arm (30/40) compared with the control group (12/16), the total number of delivered shocks was significantly lower in the protect group compared with the control group ( $P < 0.0001$ ). Moreover, freedom from the first hospitalization for HF was significantly better in the protect group than in the control group ( $P=0.038$ ).

As for the detection rate, we should select a different setting in patients with primary prevention and secondary prevention because ICD patients with primary prevention experience the faster lethal arrhythmia with an average rate of 200 beats per minute [27]. On the other hand, ICD recipients with secondary prevention indication had the appropriate ICD therapy with an average of 160 beats per minute [28]. In addition, antiarrhythmic drugs such as amiodarone are often used in these patients, which affect the VTCL and induce underdetections (Fig. 3). In fact, the risk of a slow VT above the tachycardia detection interval was about 3% (relative risk of 5%) per year during the first 4 years after ICD implantation [29]. HF prior to ICD implantation, spontaneous

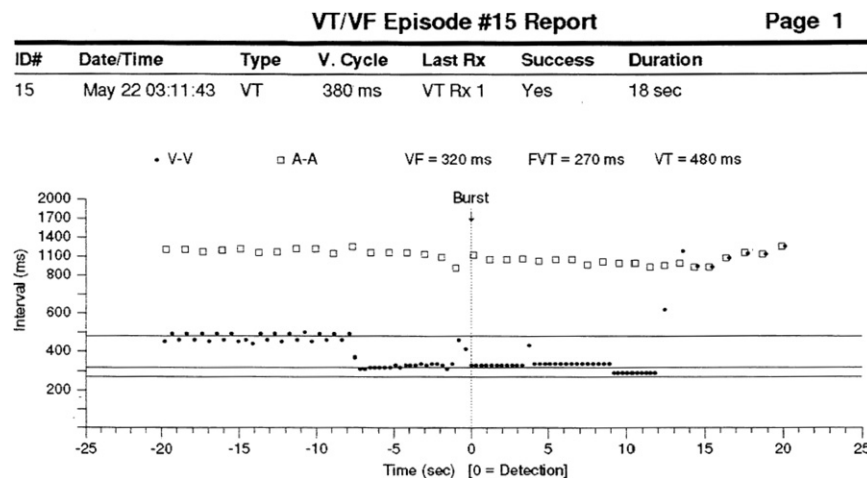
monomorphic VTs, and amiodarone use at discharge, significantly increased the risk of a VT above tachycardia detection interval. In general, cutoff intervals are often set at the appropriate values of documented or induced VT intervals with a safety margin of 30–60 ms in ICD patients with secondary prevention indication; we should therefore take into account of the risk of a slow VT above the tachycardia detection interval, particularly in ICD patients taking amiodarone. At this point, we have insufficient data regarding the relative benefits of a high cutoff rate or a longer detection interval; however, the MADIT-RIT study is now ongoing to address this issue, and this may change the settings for detection in patients with primary prevention indication.

## 5. Discriminators

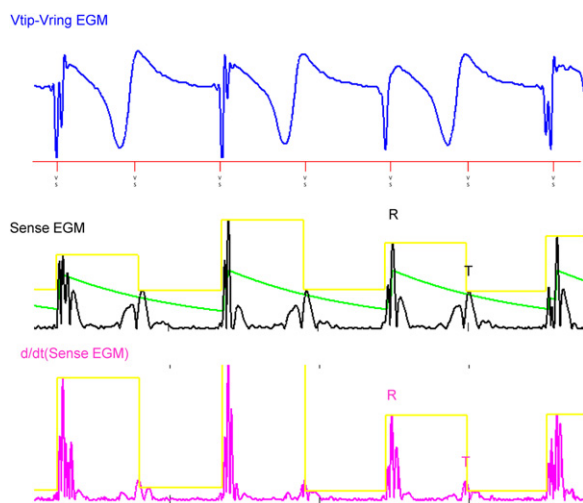
There are several algorithms for discrimination of supraventricular tachycardia (SVT) and this depends on each company's product. We usually program the discriminators up to a rate of 200 beats per minute based on its efficacy, particularly for the dual chamber system. Friedman et al. reported that more than 10% of inappropriate detection was associated with a heart rate of over 200 beats per minute [30], and based on this report, the SVT limit should nominally be set at 230 beats per minute in the most current product made by Medtronic (Protecta™). However, there is no clear evidence regarding the safety of this high rate setting, although underdetection of VF using an SVT limit of 200 beats per minute has not been reported, and we should consider the risk of overdiscrimination when withdrawing therapies for lethal arrhythmia events. On the other hand, we must use SVT discriminators in the VT zone because overlapping rates between VT and SVT were reported in ICD patients [31] and the use of SVT discriminators reduced inappropriate shocks at 1 year by 20%, without underdetection [32]. In the VT zone (relatively lower heart rate), underdetection occurs in less than 1% of true VT episodes with single or dual chamber discriminators [33–35].

## 6. Recent advances

There are several algorithms developed by suppliers to reduce mainly inappropriate shocks. Medtronic is one of leading manufacturers to address how to reduce inappropriate shocks by developing new algorithms and to fund all major shock reduction trials. A new algorithm by Medtronic, "SmartShock™ Technology" includes



**Fig. 3.** RR plots during a slow VT above the tachycardia detection interval. RR plots indicate that VT is terminated by ATP. Note that the initial RR was longer than the detection intervals, which led to delaying therapy. This patient was prescribed amiodarone.



**Fig. 4.** New algorithm for T-wave discrimination developed by Medtronic. A new algorithm for T-wave discrimination was developed to identify T-wave oversensing and provide the ability to withhold therapy delivery without compromising VT/VF detection sensitivity by discrimination of R-waves and T-waves through differential filtering of the sensing signal.

4 exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events. Adaptive PR Logic plus Wavelet is a famous algorithm that combines morphology and A-V pattern recognition to better discriminate against all types of SVT. Initially, the use of Adaptive PR Logic would occasionally misclassify SVT, such as in the case of sudden onset atrial tachycardia. The addition of Wavelet to the SVT discrimination logic will allow rhythms that are misclassified by Adaptive PR Logic to be reclassified by Wavelet so that a shock is appropriately withheld. A new algorithm for T-wave discrimination has been developed to identify T-wave oversensing and provide the opportunity to withhold therapy delivery without compromising VT/VF detection sensitivity by discrimination of R-waves and T-waves through differential filtering of the sensing signal (Fig. 4). Lead Integrity Suite is also important, which consists of RV Lead Noise Discrimination and RV Lead Integrity Alert [36]. The RV Lead Noise Discrimination algorithm analyzes a far-field electrocardiogram signal to differentiate RV lead noise from VT/VF. Confirmation+ identifies whether a tachycardia has been terminated with ATP or spontaneously during the charge and aborts the shock. Application of “SmartShock™ Technology” to the episode data from the SCD-HeFT study reduced inappropriate ICD shocks by an estimated 59%, which was confirmed by simulation [37]. Boston adopts further enhanced filtering and sensing systems with a unique auto gain control and noise window, which reduced T-wave oversensing in the real world. Moreover, we can choose between the discriminator algorithm from Rhythm ID and a classical onset/stability algorithm. Rhythm ID includes morphology defined as vector timing correlation. If patients show atrial tachycardia or atrial flutter, we should choose Rhythm ID because these arrhythmias are usually stable and have a sudden onset, which suggests difficulty in discriminating SVT from VT by using a classical onset/stability algorithm. St. Jude Medical has developed “ShockGuard™ Technology”, which includes Decision TX and a new sensing filter. Decision TX relies on new nominal settings for detection intervals, detection rate, and discriminators such as interval stability, AV association, and sudden onset, etc. The sensing filter was also changed to reduce undersensing of the R-wave and oversensing of the T-wave. “ShockGuard™ Technology” has shown a reduction of inappropriate ICD shock as well as unnecessary shocks, and the Food and Drug Administration in the USA has therefore approved

this algorithm. Sorin group and Biotronik have also developed new algorithms to reduce inappropriate ICD shock as well as unnecessary shocks.

## 7. Conclusion

ICDs have become of great use for patients with a high risk of sudden cardiac death. However, there are unresolved matters with regard to ICD, particularly regarding appropriate programming settings to avoid unnecessary shocks and inappropriate shocks. Taking into consideration the potential risk of under-detection or detrimental therapy delay for lethal arrhythmias, we must program ICD settings guided by the available evidence.

## Conflict of interest

All authors have no conflicts of interest that should be disclosed.

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